

REMARKS

Claim 1 is amended herein to recite a range of guar gum or gellan gum of “about 0.05 - about 0.3 wt.%”. Claim 1 is further amended to recite 0.1 to 20 wt.% of one masking agent selected from the group consisting of hard-to-digest dextrin and reduced hard-to-digest dextrin.

Claims 2 and 6 are canceled.

New claim 7 is added, which is directed to a preferred embodiment of the invention.

Support for the claim amendments is found, for example, at page 19, lines 5-7 and Table 5 of the specification as filed. No new matter is presented.

I. Response to Claim Rejections - 35 U.S.C. § 112

Claims 1-6 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner asserts that the specification does not provide support for the recitation of guar gum or gellan gum in an amount of 0.05-0.3% wt. The Examiner indicates that the specification provides support for guar gum or gellan gum in the gel composition of the invention is *about* 0.05 to *about* 0.3 wt%.

Without conceding the merits of the rejection, claim 1 is amended to recite the range of “about 0.05 to about 0.3 wt%” as supported by the specification at page 19, lines 5-7, thereby obviating the rejection.

Accordingly, Applicants respectfully request withdrawal of the §112 rejection.

II. Response to Claim Rejections - 35 U.S.C. § 103

1. Claims 1 and 3-4 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Fuchs et al (WO 01/01789) in view of Emoto (US 6,458,395).

Applicants traverse the rejection based on the arguments of record as set forth in the Amendment filed November 24, 2008 and further in view of the following.

As previously pointed out, the present invention is directed to a gel composition containing protein and calcium in high concentrations, with a refreshing acidic pH. In the prior art, when compositions containing protein in high concentrations are adjusted to have a refreshing acidic pH, like known jelly drinks, the compositions sometimes do not form a uniform gel due to protein coagulation, which results in a rough, coarse texture and reduced palatability. Further, compositions containing calcium in a high concentration have a high buffering effect, and require large amounts of organic acids to move their pH into the acidic range, therefore giving the composition a strong acidic taste.

In contrast, the composition of the present invention contains protein and calcium in high concentrations, but has a refreshing taste and is in the form of a soft gel suitable for eating and drinking. In order to achieve the excellent effects of the present invention, it is important to contain agar in an amount of 0.1- 1 wt% in combination with guar gum or gellan gum in an amount of 0.05 to about 0.3 wt% as recited in the present claims.

The cited references do not teach or suggest these features of the present invention.

The Examiner's position is generally that, based on the teachings of Emoto, it would have been obvious to employ a combination of agar and guar gum in the amounts recited in the present claims as the gelling agent in the composition of Fuchs based on an "obvious to try" rationale, and because the concentration of the agar and guar gum in the gelling agent would have been considered a result effective variable and/or a matter of routine optimization, absent objective evidence to the contrary.

However, to maintain a rejection under 35 U.S.C. §103, the cited references must teach or suggest each and every element of the claim. It is necessary to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some *articulated reasoning* with some *rational underpinning* to support the legal conclusion of obviousness.

In the Amendment filed November 24, 2008, Applicants pointed out that Fuchs does not teach the addition of agar to the composition, even to contain a gelling agent and that Fuchs already employs gelled protein to obtain a gelling composition. Thus, there is no apparent reason for a person skilled in the art to add further gelling agents to the composition, much less in view of Emoto.

In this connection Applicants have indicated when using generally used cation-reactive gelling agents such as gellan gum and carrageenan, it is difficult to gelate compositions containing high concentrations of protein and calcium (see page 17, paragraph 3 of the specification). However, there is no mention or recognition of the problem in Fuchs of difficulty in gelation when such high concentrations of protein and calcium are employed.

On the other hand, Emoto does not employ calcium in a concentration range similar to that of Fuchs or the present invention. Thus, there would have be no reason for one of ordinary skill in the art to expect the gelling agents disclosed by Emoto, used singly or in combination, to be suitable for addressing the problems associated with compositions having a high concentration of calcium as in Fuchs, or as in the present invention.

Moreover, the Examiner states that Fuchs discloses the gel composition comprising 2 - 4.5 wt % of protein or its hydrolysate, based on the Table at page 8, and 0.02-0.270 wt.% of calcium, based on Table 5 (see page 3, first paragraph of the Office Action). However Fuchs, states that the composition in the Table at page 8 includes 50 mg of calcium amount per 100 g, i.e., 0.05 wt.% of calcium (see pages 8-9 of Fuchs). Thus, Fuchs materially fails to disclose the composition having both protein and calcium in high concentrations.

Emoto fails to remedy the deficiencies of Fuchs. Emoto also fails to disclose a composition having both protein and calcium in high concentrations and therefore, Emoto fails to fill the gap between Fuchs and the present invention. Thus, there would have be no reason for one of ordinary skill in the art to combine the teachings of the references with a reasonable expectation of success in achieving the claimed invention.

Regarding the Examiner's position that since Emoto teaches gelling agents identical to those presently claimed, they would intrinsically be suitable for gel composition containing high concentrations of protein and calcium, Applicants note that inherency may not be established by probabilities or possibilities *if* one were to select agar of all of the gelling agents taught by Emoto since all of the gelling agents would not have provided the desired results. In this regard, Applicants have pointed out that Emoto describes various gelling agents, including cation-reactive gelling agents and when using generally used cation-reactive gelling agents such as gellan gum and carrageenan, it is difficult to gelate compositions containing high concentrations of protein and calcium (see page 17, paragraph 3 of the specification).

Regarding the Examiner's position that the features of refreshing taste and soft gel suitable for eating and drinking are not recited in the claims, Applicants respectfully submit that such features do not have to be recited in the claims. Specifically, there is no requirement that

these properties have to be recited in the claims. See, e.g., *In re Chu*, 66 F.3rd 292, 299 (Fed. Cir. 1995) where the court found that there are no cases supporting the position that a patent applicant's evidence and/or arguments traversing a § 103 rejection must be contained within the specification. Unexpected results need to be commensurate in scope with the claims, which means that the unexpected results must be due to the claimed features and not to unclaimed features. Thus, properties/effects of an invention are a result of the claimed features and need not be recited. The present claims recite a composition which is different from the prior art in that the composition requires 0.1 to 1.0 wt.% agar and about 0.05 to about 0.3 wt.% guar gum as recited in present claim 1. This difference in the composition contributes to the unexpectedly superior results of the claimed invention and therefore the claims recite the elements which distinguish the claimed invention and which contribute to the unexpectedly superior results obtained.

Also, in response to the Examiner's position that asserts that Applicants have failed to show that the gel composition of modified Fuchs would not display the taste and textural properties of the present invention, Applicants note that this is not Applicants' burden. If Applicants were to provide comparative evidence, Applicants would be required to compare the claimed invention to the closest example in the prior art. Applicants are not required to compare the claimed invention with subject matter that does not exist in the prior art. See MPEP § 716.02(e) citing *In re Chapman*, 357 F.2d 418, 148 USPQ 711 (CCPA 1966) (Requiring applicant to compare claimed invention with polymer suggested by the combination of references relied upon in the rejection of the claimed invention under 35 U.S.C. 103 "would be requiring comparison of the results of the invention with the results of the invention." 357 F.2d at 422, 148 USPQ at 714.).

Furthermore, claim 1 is amended to recite an additional ingredient of the composition, i.e., 0.1 to 20 wt.% of one masking agent selected from the group consisting of hard-to-digest dextrin and reduced hard-to-digest dextrin. This feature is not taught or suggested by the cited references. Thus, the cited references, whether taken alone or in combination do not teach or suggest all elements of the claimed invention.

In view of the above, the Examiner has not made a *prima facie* showing of obviousness. Accordingly, Applicants respectfully request withdrawal of the rejection.

2. Claims 2 and 6 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Fuchs et al (WO 01/01789) in view of Emoto (US 6,458,395) as applied to claim 1, and further in view of Ohkuma et al (US 5,364,652).

Claim 6 is canceled thereby rendering the rejection moot with respect to this claim.

Claim 2 depends from claim 1 and is patentable over Fuchs and Emoto for at least the reasons set forth above. For example, Fuchs and Emoto, taken alone or in combination, do not teach or suggest the combination of 0.1 to 1.0 wt% agar and about 0.05 to 0.3 wt% guar gum in compositions having high protein and calcium concentrations and there is no apparent reason to modify the references with a reasonable expectation of success. Ohkuma fails to remedy the deficiencies of Fuchs and Emoto.

Accordingly, Applicants respectfully request withdrawal of the rejection.

3. Claim 5 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Fuchs et al (WO 01/01789) in view of Emoto (US 6,458,395) as applied to claim 1, and further in view of Morris et al (US 5,869,118).

Claim 5 depends from claim 1 and is patentable over Fuchs and Emoto for at least the same reasons as set forth above. For example, Fuchs and Emoto, taken alone or in combination, do not teach or suggest the combination of 0.1 to 1.0 wt% agar and about 0.05 to 0.3 wt% guar gum in compositions having high protein and calcium concentrations and there is no apparent reason to modify the references with a reasonable expectation of success. Morris fails to remedy the deficiencies of Fuchs and Emoto.

Accordingly, Applicants respectfully request withdrawal of the rejection.

III. Double Patenting

1. Claims 1 and 3-5 are provisionally rejected on the ground of non-statutory double patenting over claims 1-7 of copending Application No. 10/521,170. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

2. Claims 1 and 3-5 directed to an invention not patentably distinct from claims 1-7 of commonly assigned US Appl. '170. Specifically, the Examiner states that although the conflicting claims are not identical, they are not patentably distinct.

Applicants respectfully traverse the rejections as improper.

With respect to the provisional obviousness-type double patenting rejection, the rejection is based on claims 1-7 of US '170, but the Examiner admits that US '170 does not teach a gel composition comprising 0.1-0.5 wt% calcium which was recited in claim 1 of the present application. The Examiner appears to rely on Fuchs for this limitation, but Fuchs is not included in the rejection. The rejection is based on claims 1-7 of the '170 application and the Examiner

has not otherwise indicated why the present invention is considered obvious over claims 1-7 of the '170 application alone. For at least this reason the rejection is improper.

To the extent that the Examiner may have intended to rely on Fuchs as a secondary reference, Applicants have pointed out that Fuchs states that the composition in the Table at page 8 includes 50 mg of calcium amount per 100 g, i.e., 0.05 wt.% of calcium (see pages 8-9 of Fuchs), which is outside the scope of the present claims. Thus, Fuchs materially fails to disclose the composition having both protein and calcium in high concentrations and there is no apparent reason to modify or combine the references with a reasonable expectation of success. Even if combined, the claimed invention, the claimed invention would not have been achieved.

Thus Applicants submit that the present invention is not an obvious variant to the subject matter of claims 1-7 of the '170 application.

Regarding paragraph 2 above, it is not clear what the Examiner's basis for rejection is. In the paragraph bridging pages 9-10, the Examiner states that the arguments presented in the Amendment filed February 20, 2008 were persuasive and the provisional rejection under 35 U.S.C. § 103 has been withdrawn. However, the rejection is repeated at page 9 of the Action. As noted in the Amendment filed November 24, 2008, the '170 application is not prior art under 35 U.S.C. § 102(e) or any other section of 102. Thus, Applicants request clarification of this matter and withdrawal of the rejection.

IV. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,


SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: June 22, 2009


Jennifer M. Hayes
Registration No. 40,641